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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,754	10/29/2001	Robert A. Henderson	210121.478C18	7912

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,754	HENDERSON ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 12-26* is/are pending in the application.

4a) Of the above claim(s) *1-10 and 13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group VII, claims 11 and 12 (now amended to claims 12 and 20-26) and of SEQ ID NO: 809 in the paper filed March 18, 2003 is acknowledged.

Priority

2. The current claims are drawn to methods of stimulating T-cells with an immunogenic portion of SEQ ID NO: 809. In performing the sequence search on SEQ ID NO: 809, descriptive support for the sequence was found as early as parent application 09/560,406. However, no support was found in any of the earlier filed applications by the Sequence search, at least some of which applications were in compliance with the sequence rules. Therefore, priority for this case is denied prior to 09/560,406, filed April 27, 2000, because the prior applications lack descriptive support.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 12, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Fed. Reg. Dec 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

There are two separate description issues with regard to the current claims. First, claim 12 is drawn to a "reach through" claim to T cells prepared by the method of claims 21-27. This claim encompasses a variety of T cells which are solely described in functional language as resulting from stimulation with SEQ ID NO: 809. However, there are no structural requirements which distinguish these T-cells from any other T-cells, only the functional relationship with SEQ ID NO: 809. The specification lacks any working examples of such T-cells related to SEQ ID NO: 809, so there is no written description or possession of even a single line of such T-cells.

Second, claims 24 and 26 use 90% identity language in order to encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No 809. Thus, applicant has express possession of only one particular sequence, SEQ ID NO: 809, in a genus which comprises hundreds of millions of different possibilities. No structural limitations or requirements which provide guidance on the

identification of sequences which meet these functional limitations is provided.

Further, these claims encompass alternately spliced versions of the proteins, so that the claim might be intended to capture Xage 1b and 1c, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only the specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the T-cells as made by the method of claims 21-26 is a definition by function, not a description of the material. Also, the definition of the 90% identity to SEQ ID NO: 809 lacks any specific structure and is precisely the situation of naming a type of material which is generally known to likely exist, but,

except for SEQ ID NO: 809, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to anything "90% identical to SEQ ID NO: 809".

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the T-cells or the proteins used in the method solely but their functional utility without any definition of the particular T-cells or of the particular alterations in SEQ ID NO: 809 that fall within the broad generic scope.

In the instant application, SEQ ID NO: 809 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any T-cells or of any nucleic acids other than those expressly disclosed which comprise 90% identity to SEQ ID NO: 809. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

3. Claims 21, 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by "an amino acid sequence of SEQ ID NO: 809". SEQ ID NO: 809 discloses a single amino acid sequence, so the preposition should be "the", not "an". The use of "an" implies that there are multiple sequences, such as fragments, which are intended by the claim. It is unclear if the scope of this claim is intended to include fragments, but the prior art rejection will so assume.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 12 and 20-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Yee et al (J. Immunol. (1996) 17:4079-4086) in view of Brinkmann et al (Cancer Research (1999) 59:1445-1448).

Yee teaches a method for stimulating and expanding T-cells specific for a tumor protein (see abstract) comprising: (a) Contacting T-cells with a polypeptide that is immunogenic under conditions and times sufficient to permit T-cell stimulation and expansion (see page 4080, column 2 and 4081, columns 1 and 2).

Yee repeats the method and also uses monocytic APC (antigen presenting cells) for the stimulation (see page 4081, column 2). Yee expressly suggests application of the vaccine based cancer therapy method to other immunogenic proteins (see page 4085, column 1).

Yee does not teach an immunogenic portion of SEQ ID NO: 809.

Brinkmann teaches Xage-1 (see abstract) which the attached alignment shows comprises a region of 95 amino acids which are 100% identical to SEQ ID NO: 809. This region comprises amino acids 71-90, 86-105, 96-115, 101-120, 106-125, 11-130, 116-135 and 131-150 of SEQ ID NO: 809. Brinkmann expressly suggests that this gene is a target for vaccine bases cancer therapies (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the method of Yee with the immunogenic Xage-1 protein of Brinkmann since Yee states "Employing a similar in vitro strategy with recombinant vectors expression other immunogenic proteins expressed by melanoma cells should make it possible to generate tumor reactive T-cells from most patients (see

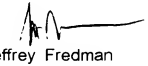
page 4085, column 1). So Yee expressly teaches and suggests generating tumor reactive T-cells using their vaccine based cancer therapy method with other immunogenic proteins. Brinkmann then motivates the specific use of Xage-1, noting "Xage-1 and Xage-2 should be evaluated as possible targets for vaccine based therapies of cancer (abstract)". Thus, an ordinary practitioner would have been expressly motivated to use the Xage-1 of Brinkmann in vaccine based cancer therapies such as the vaccine based cancer therapies of Yee in order to treat cancer since "Xage-1 may be an attractive target for therapy of muscle and bone tumors (see page 1448 of Brinkmann, column 1)."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1634

May 23, 2003